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10/809,689	03/25/2004	Mark Larche	3652/2004	7876

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EXAMINER	
ROONEY, NORA MAUREEN	
ART UNIT	**PAPER NUMBER**
1644	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/28/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/809,689	LARCHE ET AL.	
	Examiner	Art Unit	
	Nora M. Rooney	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) *8-11 and 14-29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,12 and 13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *09/22/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Notice to comply*.

DETAILED ACTION

1. Claims 1-29 are pending.

2. Applicant's election of Group I, claims 1-7 and 12-13 and the species of DR4, SEQ ID NO:2 in the reply filed on 12/13/2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The requirement is still deemed proper and is therefore made FINAL.

3. Claims 8-11 and 14-29 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

4. Claims 1-7 and 12-13 are currently under examination as they read on a method of desensitizing a patient to a polypeptide allergen comprising administering to the patient the peptide of SEQ ID NO:2 wherein restriction to DR4 possessed by the patient can be demonstrated for the peptide and the peptide is able to induce a late phase response in an individual who possesses DR4.

5. Applicant's IDS filed on 09/22/2004 is acknowledged.

6. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reasons set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. In particular, Figure 8 contains many sequences of 4 or more amino acids that lack sequence identification numbers. Correction is required.

Applicant is reminded to amend the specification (including the Brief Description of Drawings) and claims as appropriate to reflect compliance with the Sequence Rules.

Specification

7. The specification is objected to under 37 CFR 1.821(d) for failing to provide a sequence identifier for each individual sequence. Figures 8 and 9 list numerous protein sequences that each must have a sequence identifier. On page 40 of the specification, the 'Brief 'Description of the Drawings' should list the sequence identifiers for each sequence listed in Figures 8 and 9. Correction is required.

Claim Objections

8. Claim 7 is objected to because of the following informalities:

Claim 7 refers to the Fel d I-derived peptides "described in Figure 9." There are 17 "peptides" in Figure 9. In addition, such a recitation could refer to a subsequence of any of the peptides of Figure 9.

9. Claims 12-13 are objected to under 37 CFR 1.75(c) as being in improper form because: 1.) they are multiple dependent claims; 2.) the multiple dependent claims, claims 12 and 13 are dependent upon non-elected claims, claims 8-9 and 11; and 3.) claim 13 recites three separate categories of invention within a single claim by the recitation "a method according to claim 1 or a composition according to anyone of claims 8 or 9, or a pharmaceutical composition according to claim 11". In the interest of compact prosecution, Applicant is limited to a single invention within a claim. See MPEP § 608.01(n).

Claim Rejections - 35 USC § 112

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 1-7 and 12-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contains subject matter which was not

described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants are not enabled for a method of **desensitising** a patient to a **polypeptide allergen** the method comprising administering to the patient **a peptide derived from the allergen** wherein restriction to a MHC Class II molecule possessed by the patient can be demonstrated for the peptide and **the peptide** is able to induce a late phase response in an individual who possesses the said MHC Class II molecule of claim 1; wherein **the peptide** is included in a composition containing **a plurality of peptides derived** from the **said allergen** of claim 2; wherein the **plurality of peptides derived** from said allergen includes **peptides** for which restriction to Class II DR molecules DR2, DR3, DR4 and DR7 can be demonstrated, provided that such **peptides** can be derived from **the allergen** of claim 3; wherein the patient possesses any one of the MHC Class II DR molecules DR2, DR3, DR4 or DR7 of claim 4; wherein the patient possesses the MHC Class II molecule DR4 of claim 5; wherein the composition contains the Fel d I-derived peptides as given in SEQ ID Nos. 1, 2 and 3 of claim 6; wherein the composition contains the soluble MHC Class II-restricted peptides of the **Fel d I-derived peptides described in FIG. 9** of claim 7; wherein a composition according to any one of claims 8 or 9 is administered to the patient of claim 12; or a composition according to any one of claims 8 or 9, or a pharmaceutical preparation according to claim 11; or wherein the **polypeptide allergen is any one of Fel d 1, Der p I, Der p II, Der fI or Der fII** and **allergens present in any of the following: grass, tree and weed (including ragweed) pollens; fungi and moulds; foods, stinging insects, the chirnomidae (non-biting midges); spiders and mites,**

housefly, fruit fly, sheep blow fly, screw worm fly, grain weevil, silkworm, honeybee, non-biting midge larvae, bee moth larvae, mealworm, cockroach, larvae of Tenibriomolitor beetle, mammals such as cat, dog, horse, cow, pig, sheep, rabbit, rat, guinea pig, mice and gerbil of claim 13.

Factors to be considered in determining whether undue experimentation is required, are summarized in In re Wands (858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)) as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claim(s).

Pages 41-50 of the specification provide support for in vitro and in vivo methods relating to the claimed invention. 18 cat-asthmatic patients are given an intradermal injection of 3 cat allergen Fel d I peptides (SEQ ID NO 1, SEQ ID NO:2 and SEQ ID NO:3) and assessed for decreased lung function as a measure of a positive late asthmatic response (In particular, page 42, line 19 to page 43, line 13). These patients are MHC-typed by PCR. The results show that 4 of the 6 responders and 1 of the 12 non-responders are found to be HLA-DR13 (In particular, page 43, lines 17-23). All three peptides were loaded onto murine DR13 L cells and used to stimulate T cells from a whole Fel d I responder cat-allergic patient (In particular, page 43, line 25 to page 44, line 9). Proliferation of T cells was a positive indication of HLA-DR13 restriction of the T cells. The peptide of SEQ ID NO:3 presented by HLA-DR13 cells was shown to

activate the T cells. The same type of experiment showed the peptide of SEQ ID NO:3 presented by HLA-DR1 cells was shown to activate T cells. Because the peptide of SEQ ID NO:3 was shown to activate T cells when presented by HLA-DR13 and HLA-DR1 applicant determines it to be able to bind both MHC molecules and capable of inducing a late asthmatic response (In particular, page 44 lines, 11-24). Another set of experiments used murine HLA-DR4 L cells (DRB* 0404 and 0405) to stimulate T cells. A relationship between the peptide of SEQ ID NO:2 was shown for HLA-DR4 in patients "reacting" to the three peptides, presumably by intradermal injection (In particular, page 44 , line 26-30). In another in vivo experiment, 3 HLA-DR13 and/or HLA-DR1 patients were intradermally injected with the peptide of SEQ ID NO:3 (In particular, page 45, line 13 to page 46, line 7). T-cells from these patients were shown to proliferate in response to the peptide of SEQ ID NO:3 presented by murine HLA-DR1 or HLA-DR13 cells prior to the injection. The patients all experienced a late phase response as demonstrated by decreased lung function. The patients were challenged again after two weeks, but no late phase response was seen. Therefore, applicants disclose that the immune response to the peptide was down-regulated (In particular, page 46, lines 5-7). Applicants also disclose the in vitro MHC restriction mapping of Fel d I derived peptides using HLA-DR -DP and -DQ type clones for use in a database (IN particular, page 46, line 11 to page 47, line 20). Further, applicants disclose a method for the identification of MHC-restricted peptides using overlapping peptides (In particular, page 47, line 26 to page 50, line 5).

The specification does not provide support for a method of "desensitization" of a patient to an allergen because the term implies permanent tolerance to the allergen. The art shows that

the recited method does not fully "desensitize" a patient to the allergen as shown by Haseldon et al. (PTO-892, Reference U, page 1893, left and right columns). In this reference, three subjects who were administered the peptide of SEQ ID NO:1 were re-administered the peptide of SEQ ID NO:1 at the same dose at least one year later. According to the reference, all three patients "developed LARs of approximately the same magnitude as those that accompanied the initial challenge." Therefore, the hyporesponsiveness induced by the initial challenge is short-lived and does not result in the "desensitization" of the patient. The reference suggests that the repeated administration of the peptide may induce long-term tolerance, but that it is unpredictable because the studies have not yet been done.

The specification does not provide support for a method of desensitizing a patient to "a polypeptide allergen" of claim 1, a polypeptide allergen from "Fel d 1, Der p I, Der p II, Der fI or Der fII of claim 13 or allergens present in grass, tree and weed (including ragweed) pollens; fungi and moulds; foods, stinging insects, the chirnomidae (non-biting midges); spiders and mites, housefly, fruit fly, sheep blow fly, screw worm fly, grain weevil, silkworm, honeybee, non-biting midge larvae, bee moth larvae, mealworm, cockroach, larvae of Tenibriomolitor beetle, mammals such as cat, dog, horse, cow, pig, sheep, rabbit, rat, guinea pig, mice and gerbil of claim 13. The specification data in Example 2, pages 42-43, highlights the unpredictability of the art. 18 patients who were allergic to cats were given a combination of the peptide of SEQ ID NO:1, SEQ ID NO:2 and SEQ ID NO:3 and 12 patients did not exhibit an LAR. Therefore, even using "any peptide" of one specific allergen, in this case Fed d I, that exhibits the claimed

functional features is highly unpredictable, much less any peptide from any polypeptide allergen. Further, Francis et al. (PTO-892, Reference W, abstract) teaches that data from clinical trials shows that peptide based vaccination was associated with "a modest improvement in allergic disease" but that it was "accompanied by a high frequency of adverse reactions." The reference suggests that "manipulation of peptide epitopes may provide a strategy for the rational design of peptide allergy vaccine further improving safety and efficacy." Furthermore, the specification only provides experimental data using the peptide of SEQ ID NO:3 to provide support for the claimed "desensitization" method as demonstrated by a decreased or reduced LAR after a second administration two weeks following the first administration in 3 patients (In particular, pages 45, line 28 to page 46, line 7). No other peptide or allergen, including the peptide of SEQ ID NO:2, was ever shown in the specification to desensitize a patient. One of ordinary skill in the art would be required to perform a great amount of experimentation in order to identify allergens and peptides with the claimed functional characteristics to practice the claimed invention. Therefore, the art shows that administering peptide to desensitize allergic patients in unpredictable and would require undue experimentation to practice the claimed invention.

The specification does not provide support for a method of desensitizing a patient comprising administering "a peptide derived from the allergen." The claims, as recited, include the use of any peptide from any polypeptide allergen or any derivative thereof. Kinnunen et al. (PTO-892, Reference V, abstract, discussion) teaches that the use of allergen peptide derivatives or "altered peptide ligands" of the lipocalin allergen. The reference shows that the APL induce differential T cells stimulation (In particular, Table I, page 6, paragraph spanning left and right

columns). The discussion cautions those who are looking to use APL in immunotherapy for allergy because some T cells populations, such as pathogenic memory cells, that are induced by certain APL would exacerbate allergic disease (In particular, page 7, left column, second paragraph). One of ordinary skill in the art would be required to determine how alterations to each position of the peptide affect binding to MHC and how that in turn effects T cell activation. The T cell activation induced by the peptide in vivo would also need to promote hypoallergenic/tolerogenic effects, which is also highly unpredictable. The unpredictibility in the art highlights that an undue amount of experimentation is necessary to practice the claimed invention.

The specification does not provide support for a method of desensitizing a patient wherein the peptide is in a composition containing "a plurality of peptides derived from the said allergen." In the same way as above, the specification does not provide adequate support for the desensitization of patients with any peptide of any allergen, nor does it support the administration of one or more of these peptides because it would required an undue amount of experimentation to know which peptides have the claimed functional characteristics and could be used in the claimed invention.

Reasonable correlation must exist between the scope of the claims and scope of the enablement set forth. In view on the quantity of experimentation necessary the limited working examples, the nature of the invention, the state of the prior art, the unpredictability of the art and the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

12. Claims 1-7 and 12-13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Applicant is in possession of the peptides of SEQ ID NO: 1, SEQ ID NO:2 and SEQ ID NO:3 for stimulating T cells in vitro.

Applicant is not in possession of a method of desensitising a patient to a **polypeptide allergen** the method comprising administering to the patient **a peptide derived from the allergen** wherein restriction to a MHC Class II molecule possessed by the patient can be demonstrated for the peptide and **the peptide** is able to induce a late phase response in an individual who possesses the said MHC Class II molecule of claim 1; wherein **the peptide** is included in a composition containing **a plurality of peptides derived** from the **said allergen** of claim 2; wherein the **plurality of peptides derived** from said allergen includes **peptides** for which restriction to Class II DR molecules DR2, DR3, DR4 and DR7 can be demonstrated, provided that such **peptides** can be derived from **the allergen** of claim 3; wherein the patient possesses any one of the MHC Class II DR molecules DR2, DR3, DR4 or DR7 of claim 4; wherein the patient possesses the MHC Class II molecule DR4 of claim 5; wherein the composition contains the Fel d I-derived peptides as given in SEQ ID Nos. 1, 2 and 3 of claim 6;

wherein the composition contains the soluble MHC Class II-restricted peptides of the **Fel d I-derived peptides described in FIG. 9** of claim 7; or wherein a composition according to any one of claims 8 or 9 is administered to the patient of claim 12; or a composition according to any one of claims 8 or 9, or a pharmaceutical preparation according to claim 11 wherein the polypeptide allergen is any one of Fel d 1, Der p I, Der p II, Der fI or Der fII and **allergens present in any of the following: grass, tree and weed (including ragweed) pollens; fungi and moulds; foods, stinging insects, the chirnomidae (non-biting midges); spiders and mites, housefly, fruit fly, sheep blow fly, screw worm fly, grain weevil, silkworm, honeybee, non-biting midge larvae, bee moth larvae, mealworm, cockroach, larvae of Tenibriomolitor beetle, mammals such as cat, dog, horse, cow, pig, sheep, rabbit, rat, guinea pig, mice and gerbil** of claim 13.

The specification does not provide adequately describe a method of desensitizing a patient to "a polypeptide allergen" of claim 1, " a peptide derived from an allergen" of claim 1, "a peptide of the Fel d I-derived peptides described in Figure 9" of claim 7; a polypeptide allergen from "Fel d 1, Der p I, Der p II, Der fI or Der fII of claim 13 or allergens present in grass, tree and weed (including ragweed) pollens; fungi and moulds; foods, stinging insects, the chirnomidae (non-biting midges); spiders and mites, housefly, fruit fly, sheep blow fly, screw worm fly, grain weevil, silkworm, honeybee, non-biting midge larvae, bee moth larvae, mealworm, cockroach, larvae of Tenibriomolitor beetle, mammals such as cat, dog, horse, cow, pig, sheep, rabbit, rat, guinea pig, mice and gerbil" of claim 13; or "a plurality of peptides derived from the said allergen" of claim 3. Applicant has not provided an adequate written

description of the claimed peptides and allergens such that one would be able to determine which peptides possessed the required functional characteristics for use in the invention.

Adequate written description requires more than a mere statement that it is part of the invention. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC1993). The Guidelines for the Examination of Patent Application Under the 35 U.S.C.112, ¶ 1"Written Description" Requirement make clear that the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species disclosure of relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 20001, see especially page 1106 3rd column).

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.). Consequently, Applicant was not in possession of the instant claimed invention. See University of California v. Eli Lilly and Co. 43 USPQ2d 1398.

Applicant is directed to the final Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 1-7 and 12-13 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 97/35193 (PTO-892, Reference N).

WO 97/35193 teaches a method of desensitizing a patient to a polypeptide allergen comprising the administration of the claimed peptide of SEQ ID NO:2 (peptide, polypeptide allergen, peptide derived from the allergen, Fel d I derived allergen) (100% identity over length and sequence) to treat atopic disease (desensitize) by administering the peptide to a patient (In particular, Claim 12, SEQ ID NO:1, Figure 1 (Peptide 4), page 6, lines 15-26). The peptide can be administered in a composition (In particular, page 6, line 27 to page 7, line 29) and the composition may include other peptides (a plurality of peptides) (In particular, page 9, lines 13-16). The recitations of "wherein restriction to a MHC Class II molecule possessed by the patient

can be demonstrated for the peptide" and "the peptide is able to induce a late phase response in an individual who possesses the said MHC Class II molecule" of claim 1; wherein the plurality of peptides derived from said allergen includes "peptides for which restriction to Class II DR molecules DR2, DR3, DR4 and DR7 can be demonstrated", provided that such peptides can be derived from the allergen of claim 3; wherein "the patient possesses any one of the MHC Class II DR molecules DR2, DR3, DR4 or DR7" of claim 4; wherein "the patient possesses the MHC Class II molecule DR4" of claim 5 are inherent as the same peptide is being administered to the same patient population for the same result.

The reference teachings anticipate the claimed invention.

15. Claims 1-7 and 12-13 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 91/06571 (PTO-892, Reference O).

WO 91/06571 teaches a method of desensitizing a patient to a polypeptide allergen comprising the administration of a 94 amino acid peptide comprising the peptide of SEQ ID NO:2 (peptide, polypeptide allergen, peptide derived from the allergen, Fel d I derived allergen) (Figure 1, claims 2 and 26) to reduce or prevent the adverse effects of cat allergen exposure in cat allergic individuals(desensitize) by administering the peptide to a patient (In particular, paragraph spanning pages 3 and 4). The peptide can be administered in a composition (In particular, paragraph spanning pages 3 and 4) and the composition may include other peptides (a plurality of peptides) (In particular, paragraph spanning pages 3 and 4). The recitations of

"wherein restriction to a MHC Class II molecule possessed by the patient can be demonstrated for the peptide" and "the peptide is able to induce a late phase response in an individual who possesses the said MHC Class II molecule" of claim 1; wherein the plurality of peptides derived from said allergen includes "peptides for which restriction to Class II DR molecules DR2, DR3, DR4 and DR7 can be demonstrated", provided that such peptides can be derived from the allergen of claim 3; wherein "the patient possesses any one of the MHC Class II DR molecules DR2, DR3, DR4 or DR7" of claim 4; wherein "the patient possesses the MHC Class II molecule DR4" of claim 5 are inherent as the same peptide is being administered to the same patient population for the same result. Claim 6 is included in the rejection because the term "contains" is open language and includes the peptide of SEQ ID NO:2 with additional amino acids, as the peptide of claim 2 of WO 91/06571.

The reference teachings anticipate the claimed invention.

16. Claims 1-7 and 12-13 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 93/08280 (PTO-892, Reference P).

WO 93/08280 teaches a method of desensitizing a patient to a polypeptide allergen comprising the administration of a 92 amino acid peptide containing the peptide of SEQ ID NO:2 (peptide, polypeptide allergen, peptide derived from the allergen, Fel d I derived allergen) (Figure 1, Claim 1) in a desensitization treatment of protein allergic individuals by administering the peptide to a patient (In particular, claim 45). The peptide can be administered in a

composition (In particular, claim 42) and the composition may include other peptides (a plurality of peptides) (In particular, claim 1). The recitations of "wherein restriction to a MHC Class II molecule possessed by the patient can be demonstrated for the peptide" and "the peptide is able to induce a late phase response in an individual who possesses the said MHC Class II molecule" of claim 1; wherein the plurality of peptides derived from said allergen includes "peptides for which restriction to Class II DR molecules DR2, DR3, DR4 and DR7 can be demonstrated", provided that such peptides can be derived from the allergen of claim 3; wherein "the patient possesses any one of the MHC Class II DR molecules DR2, DR3, DR4 or DR7" of claim 4; wherein "the patient possesses the MHC Class II molecule DR4" of claim 5 are inherent as the same peptide is being administered to the same patient population for the same result. Claim 6 is included in the rejection because the term "contains" is open language and includes the peptide of SEQ ID NO:2 with additional amino acids, as the peptide of Figure 1 of WO 93/08280.

The reference teachings anticipate the claimed invention.

17. Claims 1-7 and 12-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Norman et al. (Reference 17, IDS filed on 09/22/2004)

Norman et al. teaches a method of desensitizing a patient to a polypeptide allergen comprising the administration of the two 27 amino acid long IPC-1 and IPC-2 peptides containing the peptides of SEQ ID NO:1 and SEQ ID NO:2, respectively (peptide, polypeptide allergen, peptide derived from the allergen, Fel d I derived allergen) (Figure 1) for treating cat allergy by administering the peptides to cat allergic patients by subcutaneous injection (In

particular, page 1624 'Study Design' section). The peptide can be administered in a composition (In particular, page 1624, 'Treatment Peptides' section) and the composition may include other peptides (a plurality of peptides) (In particular, page 1628, right column, first paragraph). The recitations of "wherein restriction to a MHC Class II molecule possessed by the patient can be demonstrated for the peptide" and "the peptide is able to induce a late phase response in an individual who possesses the said MHC Class II molecule" of claim 1; wherein the plurality of peptides derived from said allergen includes "peptides for which restriction to Class II DR molecules DR2, DR3, DR4 and DR7 can be demonstrated", provided that such peptides can be derived from the allergen of claim 3; wherein "the patient possesses any one of the MHC Class II DR molecules DR2, DR3, DR4 or DR7" of claim 4; wherein "the patient possesses the MHC Class II molecule DR4" of claim 5 are inherent as the same peptide is being administered to the same patient population for the same result. Claim 6 is included in the rejection because the term "contains" is open language and includes the peptide of SEQ ID NO:2 with additional amino acids, as the IPC-1 and IPC-2 peptides of Figure 1.

The reference teachings anticipate the claimed invention.

18. No claim is allowed.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nora M. Rooney whose telephone number is (571) 272-9937. The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by

telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

March 16, 2007

MAHER M. HADDAD
PRIMARY EXAMINER

Nora M. Rooney, M.S., J.D.

Patent Examiner

Technology Center 1600

Notice to Comply	Application No.	Applicant(s)	
	10/809,689	LARCHE ET AL.	
	Examiner	Art Unit	
	Nora M. Rooney	1644	

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☒ 7. Other: There are numerous sequences in Figure 8 that have no sequence indentification numbers. In addition, the sequences are not included in the Sequence Listing, CRF and Specification.

Applicant Must Provide:

☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

☒ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216
For CRF Submission Help, call (703) 308-4212
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